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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,285	03/02/2005	Nitin Bhalachandra Dharmadhikari	006420.00004	4683

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EXAMINER	
SIMMONS, CHRIS E	

ART UNIT	PAPER NUMBER
1612	

MAIL DATE	DELIVERY MODE
10/06/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/526,285	DHARMADHIKARI ET AL.	
	Examiner	Art Unit	
	CHRIS E. SIMMONS	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 May 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,7,10,11,14-18,23 and 29-31* is/are pending in the application.

4a) Of the above claim(s) *29 and 30* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *1,7,10,11,14-18,23 and 31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/06/2010 has been entered.

Applicants' arguments, filed 05/06/2010, have been fully considered. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Election/Restrictions

Applicant submits that claim 30 should be rejoined with claim 31. Examiner disagrees because claim 30 is directed to a materially different invention as outlined previously in the 03/18/2009 Office action at page 2. Accordingly, the restriction requirement between the product and process claims, including claim 29, is still deemed proper and is now made FINAL.

Response to Arguments

Applicant's arguments, see page 7, lines 13-14, filed 05/06/2010, with respect to the claims being obvious over Martin et al. have been fully considered and are persuasive. Applicant's argument that Martin et al. do not identify any specific particle sizes or range of particle sizes of any drug is well received. The obviousness rejection over Martin et al. in view of Scaife et al. of the claims has been withdrawn.

Claim Rejections - 35 USC § 103

Claims 1, 7, 10, 11, 14-18, 23 and 31 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Motoyama et al. (US 4,540,602) in view of Scaife et al. (US 6,407,128).

Motoyama discloses activated pharmaceutical compositions with such good redispersibility that, after oral administration, it is rapidly carried to the small intestine and readily absorbed into the blood to raise its blood concentration quickly. This process is carried out by providing a solid drug that is scarcely soluble in water (relevant to claim 7), dispersing the drug in water in the presence of a water-soluble high-molecular substance to form a disperse system containing the drug in the form of finely divided particles substantially not greater than 10 microns in diameter. (See abstract). The diameter of redispersed particles can be within the range of 0.8 to 3.5 microns (see Example 7). The examples demonstrate specific amounts of solid drugs ranging from 4mg to 50g.

Sodium lauryl sulfate (relevant to claim 18) is a known surfactant, commonly used in the preparation of pharmaceutical products and would have been obvious to use as a surface-active agent in the Motoyama formulation with solid drug that is scarcely soluble in water.

Scaife discloses metaxolone is a hydrophobic drug that is useful for treating pain and can benefit from addition to compositions that can increase its bioavailability. About 200 to about 900 mg (400mg is exemplified) of metaxalone are therapeutic (col. 2, ll. 23-24). Metaxalone is a central nervous system depressant that has sedative and skeletal muscle relaxant effects. Metaxalone is indicated as an adjunct to rest, physical therapy and other measures for the relief of discomforts associated with acute, painful muscoloskeletal conditions (col. 1, ll. 21-23).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the activated pharmaceutical compositions described by Motoyama by adding metaxalone as the drug with low water solubility as Scaife describes metaxalone as a hydrophobic drug that is in need of increased bioavailability. Because Motoyama describes compositions that would increase the bioavailability of drugs with low solubility the skilled artisan have had a reasonable expectation that the composition described by Motoyama would increase the bioavailability of metaxalone.

Regarding claim 23, although Scaife et al. do not particularly recite a pharmaceutical composition comprising metaxalone and another analgesic, combining agents which are known to be useful as analgesics individually into a singe composition useful for the very same purpose is *prima facie* obvious. See In re Kerkhoven 205

USPQ 1069. Since it is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose, the idea of combining analgesics flows logically from their having been individually taught in the prior art.

Response to arguments relevant to the new rejection

Applicant asserts that Scaife teaches a method for increasing the extent of absorption of a form of metaxalone by administering it with food, but reports the increased *extent* of absorption corresponds with a decrease in the *rate* of absorption. Thus, Applicants assert that Scaife et al teaches an inverse relationship between extent of absorption and rate of absorption.

The examiner submits that these arguments are not persuasive and does not support the claim of unexpected results.

It is noted that applicant again cites Table IIb of Scaife as evidence that an increase in the extent and rate of absorption are inversely correlated which allegedly supports the claim of achieving unexpected benefits of the current invention by increasing both rate and extent of absorption simultaneously. As such one cannot rely only on Tmax alone to make a definitive conclusion on the rate of absorption. This is supported by Scaife et al. who have demonstrated an increase in extent and rate of absorption (col. 2, lines 7-8) even though Tmax was increased (see Table IIb) when metaxalone was administered with food. Further more, as explained in the 06/26/2008 Office action at page 7 and the 03/18/2009 Office action at page 9, Tmax is a function of

elimination or excretion and is unreliable by itself as an indicator of rate of absorption. Looking at Table IIb, it would appear that since Tmax in the group with food is 4.29 hours and the Cmax is 1774 ng/mL then the rate of absorption would be 413 ng/mL/hour (i.e., 1774 ng/mL / 4.29 hours) for subjects with food. For subjects without food the rate of absorption would appear to be 296 ng/mL/hours (i.e., 983 ng/mL / 3.32 hours). Therefore, since 413 ng/mL/hour are absorbed in subjects with food and only 26 ng/mL/hour are absorbed in subjects without food, then Scaife et al. teach an increase rate of absorption in subjects with food. As such, applicant's argument that Scaife et al. teach that the rate of absorption of metaxalone is decreased when metaxalone is administered with food is incorrect. Thus Scaife et al. do not teach the inverse relationship between extent of absorption and rate of absorption alleged by applicant.

Conclusion

No claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to CHRIS E. SIMMONS whose telephone number is (571)272-9065. The examiner can normally be reached on Monday - Friday from 7:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Allison M. Ford/
Primary Examiner, Art Unit 1651

/C. E. S./
Examiner, Art Unit 1612